UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/765,696	01/19/2001	Daniel S. Sem	P-TB 4567	6467

23601 7590 08/10/2004

CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/765,696	SEM, DANIEL S.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/29/04 has been entered.

2. The after final amendment filed on 12/1/03 has been fully considered and entered into the application. New claims 57-59 have been added by the amendment filed on 12/1/03.

3. Claims 44-59 are currently present and are being examined in this application.

4. This application lacks the necessary reference to the prior application. A statement reading "This is a Divisional of Application No. 09/083,537, filed 5/21/98." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of the parent nonprovisional application(s) should be included.

Claim Objections

5. Claims 52 and 57 are duplicate claims, the scope of the claims is the same. Applicant is required to cancel the claim(s), or amend the claim(s).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 44-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The instant claim 44 recites a method for identifying a population of bi-ligands to dehydrogenase in a dehydrogenase family, comprising : a) attaching a linker to a common ligand, wherein the common ligand is a cofactor or a mimic thereof, and the linker has sufficient length and orientation to direct a second ligand to a substrate binding site of dehydrogenase to form a module;

b) generating a population of bi-ligands comprising a second ligand and the module;

c) screening said population of bi-ligands for binding to a dehydrogenase in said dehydrogenase family;

d) identifying a bi-ligand that binds to and has specificity to said dehydrogenase; and

e) repeating steps c-d to identify a bi-ligand that binds to has a specificity for a second dehydrogenase in said dehydrogenase family.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The instant claims are directed to a "population" of "bi-ligands". The claims use generic terminology such as "common ligand", "conserved

site", "specificity ligand", "specificity site", "receptor family" and "expansion linker". These terms are defined in the instant disclosure but the definitions are very broad.

The specification discloses that the 'common ligand' is a ligand that binds to a conserved site in a receptor family; 'specificity ligand' refers to a ligand when attached to a common ligand binds to a specificity site on a receptor that is proximal to the conserved site; and 'expansion linker' is a chemical group that is capable of linking two ligands.

The specification discloses that receptor family is identified based on conserved and recognizable motif and in public databases. The specification lists the known common ligands to a certain receptor families. The specification further discloses methods for selecting common ligands and the use of NMR in determining the common ligand and determining the orientation which are useful in designing or synthesizing the bi-ligands. The specification has not disclosed the common ligands identified by the method or any mimics of the common ligand used in the synthesis of bi-ligands.

The specification discloses methods for screening and/or NMR experiments to confirm the common ligand-expansion linker (module) binds to the conserved site in correct orientation. Once a common ligand-expansion linker has been identified that binds to the conserved site in correct orientation for attaching a specificity ligand to the expansion linker, a population of bi-ligands are generated, which are screened for binding to a target receptor. The specification discloses that the method is useful in screening for high affinity, high specificity ligands to a target receptor. Thus, the bi-ligands of the claimed method are useful in further screening for a target or to identify the ligands.

The specification discloses that an expansion linker that provides an optimized orientation for attaching the specificity ligand is determined by further screening or experimentations.

The specification has not disclosed the mimics of the common ligands; the expansion linker and/or attachment site to the common ligand such that specificity ligand binds to the linker, and the common ligand-expansion linker (module) identified in generating the bi-ligands, and the bi-ligands identified by the claimed method.

No specific structure of the identified "bi-target ligand" is set forth and no specific "method for identifying a bi-target ligand" is described in the instant disclosure. Note that the recitation of dehydrogenase enzyme and the NAD or NADP as cofactors does not sufficiently teach the claimed invention. The structure of the claimed bi-ligands cannot be determined by the dehydrogenase enzyme or the cofactors. And further the identified bi-lgands are screened for bi-ligand that binds to and has specificity for a second dehydrogenase in the dehydrogenase family, which is required further experimentation. The exemplary figure 3 of the instant specification does not show the structure of the ligands. The present application fails to describe a specific example of identifying even a single compound, which is within the scope of the presently claimed invention. Applicant's claimed scope represents only an invitation to experiment regarding possible identified "bi-target ligands" within the scope of the claims.

The specification discloses no examples of the preparation and use of such "bi-ligands". These compounds (i.e. "common ligand" and "specificity ligand") could encompass very different moieties such as peptides and organic molecules. Additionally, the description of "conserved site" as residues that are sufficient for activity

(specification, pages 13-14) and "specificity site" as a binding site for a ligand exhibiting specificity for a receptor (specification, page 15) are simply not adequate support to show possession of the claimed invention.

With respect to adequate disclosure of the scope of the presently claimed generic applicant is referred to the discussion in *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175) regarding disclosure. For adequate disclosure, like enablement, requires representative examples, which provide reasonable assurance to one skilled in the art that the compounds falling within the scope both possess the alleged utility and additionally demonstrate that applicant had possession of the full scope of the claimed invention. See *In re Riat* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr_* (CCPA 1971) 444 F 2d 349, 151 USPQ 724 (for enablement) and *University of California v. Eli Lilly and Co* cited above (for disclosure). The more unpredictable the art the greater the showing required (e.g. by "representative examples") for both enablement and adequate disclosure.

The disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Moreover, the claimed genus encompasses members, which are yet to be prepared or envisioned. This further evidences that instant disclosure does not constitute support for the claimed genus or a substantial portion thereof.

7. Claims 44-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim 44 recites a method for identifying a population of bi-ligands to dehydrogenase in a dehydrogenase family, comprising : a) attaching a linker to a common ligand, wherein the common ligand is a cofactor or a mimic thereof, and the linker has sufficient length and orientation to direct a second ligand to a substrate binding site of dehydrogenase to form a module;

b) generating a population of bi-ligands comprising a second ligand and the module;

c) screening said population of bi-ligands for binding to a dehydrogenase in said dehydrogenase family;

d) identifying a bi-ligand that binds to and has specificity to said dehydrogenase; and

e) repeating steps c-d to identify a bi-ligand that binds to has a specificity for a second dehydrogenase in said dehydrogenase family.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include, but are not limited to:

(1) the breadth of the claims;
(2) the nature of the invention;
(3) the state of the prior art;
(4) the level of one of ordinary skill;
(5) the level of predictability in the art;
(6) the amount of direction provided by the inventor;
(7) the existence of working examples; and
(8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims and the nature of the invention: The claims are drawn to a "method for identifying a bi- ligand to dehydrogenase" wherein the "bi-ligand" is made up of three parts: a "common ligand", a "second ligand" and "a linker." No limitations on the specific structure of the identified "bi-ligand" are given and, as such, this could read on a wide variety of structures. The invention is such that each of the components must be present in operable form for successful practice of the invention. For example, the "common ligand" and "second ligand" must bind to their respective sites on the receptor and the sites must be able to be determined.

The state of the prior art and the level of predictability in the art: Compounds that interact with various enzyme targets were known in the art at the time of filing; however, only limited numbers of such compounds were known and the specification gives no guidance to permit one of skill in the art to devise strategies for synthesis of *any* such compound. The identified "bi-ligands" of the instant claims require "common ligands" and "second ligand"; however, such bi-ligands for enzyme families were not generally known in the art. And further the instant claim recites that the bi-lgands which are identified in step d) are use din further screening for a bi-ligand that binds to and has specificity to a second dehydrogenase in dehydrogenase family. The bi-ligand of the instant claim has the following three components, 1) a common ligand binds to the conserved site on the receptor, 2) the specificity ligand binds to the specificity site proximal to the conserved site, and 3) the linker linking the common ligand and the specificity ligand, thus it is not clear how the bi-ligands of the instant claims bind to and has specificity to a second dehydrogenase in dehydrogenase family. The structures of possible variants are sufficiently diverse and one of ordinary skill would not be able to

predict their structures. Moreover, the claims require the presence of a "common ligand" which is a "cofactor " or is a "**cofactor mimic**" and additional ligand that bind to "substrate binding sites" of a first and a second enzyme in an "enzyme family". One of ordinary skill would not know, *a priori*, how to determine the structure of such ligands because the determination of the different binding sites in an "enzyme family" would be unpredictable. Applicant's claimed scope of compounds represents only an invitation to experiment regarding possible methods of identification of undefined "bi-ligands" (see also above rejection concerning written description and cases cited therein). The expansion linker which links the common ligand and the specificity ligand length or the compound structure is not known such that when the linker binds to the common ligand or mimic of the common ligand a specificity linker can be attached such that the specificity linker binds to the specificity site on the receptor and the common ligand binds to the conserved site of the receptor. Note that the recitation of dehydrogenase enzyme and the NAD or NADP as cofactors does not sufficiently teach the claimed invention. Further the specification has not disclosed the length or the orientation of the linker such that second ligand is positioned such that the second ligand binds the specificity site on the receptor.

The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. However, such persons of ordinary skill in this art, *given its unpredictability*, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

The existence of working examples and the quantity of experimentation needed to

make or use the invention based on the content of the disclosure: Applicants have provided **no** working examples and the state of the prior art is such that one of ordinary skill could not predict how to determine and then link the various moieties that make up the identified "bi-ligand" as required by the instant claims. Therefore, further research would be necessary to make or use the invention and it would require undue experimentation to carry out the invention as claimed. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the invention would require undue experimentation.

8. Claims 44-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The 'mimic thereof' claimed in Claims 44-59 has no clear support in the specification and the claims as originally filed. (Note the term 'mimic' was introduced with the amendment, filed on 8/12/02). The subject matter claimed in claims 44-59 broadens the scope of the invention as originally disclosed in the specification.

If applicants disagree, applicant should present a detailed analysis as to why the claimed subject matter has clear support in the specification

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 44-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 44, 47, 52 are vague and indefinite by reciting 'mimic thereof', however the specification has no definition for common ligand mimic. It is not clear what is metes and bounds of the term 'mimic', does applicants mean the structural mimic or functional mimic.

Claims 44-59 are vague indefinite by reciting 'linker has sufficient length and orientation', which is not clear since the specification has not given any guidance or definition for determining the length or the orientation of the linker.

Claims 44-59 are vague and indefinite by reciting 'step e', in which bi-ligands that bind to has specificity for a second dehydrogenase in said dehydrogenase family is identified. Does applicants mean that the bi-ligands of the instant claims bind to more than one dehydrogenase. The bi-ligand of the instant claim has the following three components, 1) a common ligand binds to the conserved site on the receptor, 2) the specificity ligand binds to the specificity site proximal to the conserved site, and 3) the linker linking the common ligand and the specificity ligand, thus it is not clear how the

bi-ligands of the instant claims bind to and has specificity to a second dehydrogenase in dehydrogenase family.

Claims 44-59 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: The screening step in step e, where the bi-ligands identified in step d used in screening for binding to a second dehydrogenase in the dehydrogenase family.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 44-59 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The instant claim 44 recites a method for identifying a population of bi-ligands to dehydrogenase in a dehydrogenase family, comprising : a) attaching a linker to a common ligand, wherein the common ligand is a cofactor or a mimic thereof, and the linker has sufficient length and orientation to direct a second ligand to a substrate binding site of dehydrogenase to form a module;

b) generating a population of bi-ligands comprising a second ligand and the module;

c) screening said population of bi-ligands for binding to a dehydrogenase in said dehydrogenase family;

d) identifying a bi-ligand that binds to and has specificity to said dehydrogenase; and

e) repeating steps c-d to identify a bi-ligand that binds to has a specificity for a second dehydrogenase in said dehydrogenase family.

(NOTE that independent claim 44 is similar in scope with other independent claims.)

According to the text of 35 USC sec. 101, an invention must be "useful". Our reviewing courts have applied the labels, "specific utility" (or "practical utility") to refer to this aspect of the "useful invention" requirement of sec. 101. (Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881, 883 (CCPA 1980)). In Nelson, the court characterized "specific utility" (or "practical utility") as "a shorthand way of attributing real-world value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner, which provides some immediate benefit to the public." (Id. at 856.)

Note that the recitation of dehydrogenase enzyme and the NAD or NADP as cofactors does not impart any specific utility of the claimed method bi-ligands. The structure of the claimed bi-ligands cannot be determined by the dehydrogenase enzyme or the cofactors. The bi-target ligand (common ligand, specificity ligand linked via an expansion linker) to enzyme and the population of bi-ligands (common ligand – linker – specificity ligand) of the claimed method are not supported by a specific asserted utility and do not, without further research and experimentation, provide an immediate benefit to the public. Rather, the bi-ligand comprises compounds , which are yet to be tested for their therapeutic activity. For example, the instant specification, (page 12, 0103 on PG PUB US 2001/0006822 A1) discloses that the bi-ligand can be validated as a likely effective therapeutic agent (if the target receptor is a pathogenic organism, the bi-ligand

can be tested for inhibitory activity in the target organism). Thus, the bi-ligands have to be further tested for activity. Thus, any benefit to the public (to one of ordinary skill in the art) is speculative. There is no basis in the specification upon which to conclude that *any* of the compounds encompassed by bi-target or the bi-ligand of the instant claims **are**, or will turn out to be, biologically active after testing. The therapeutic use of the bi-target ligand is to take place at some future time, only when the properties of the bi-ligands have been elucidated by the experimental methods (screening assays). Absent a disclosure of those properties, the asserted utility of therapeutic use lacks specificity.

Further the specification discloses that the common ligand-expansion linker (module) have to be screened to identify the common-ligand in that the linker is attached to the common ligand oriented towards the specificity site. The expansion linker that provides the optimized orientation for attaching a specificity ligand has to be identified. Thus, further experimentation in determining the common ligand, expansion linker is required.

The instant specification discloses that the bi-ligands (common ligand – linker – specificity ligand) act as therapeutic agents. A "specific utility" is specific to the subject matter claimed. This is contrast with a general utility that would be applicable to the broad class of invention. Indicating the compound may be useful in treating a disorder (bacterial infection) or has useful biological properties would not be sufficient to define specific utility of the compound (e.g., see MPEP 2107.01). Further the specification has not shown the correlation between the similar known compounds, which have established utility and/or data from in vivo or in vitro testing of the compounds to support the therapeutic utility.

Note, because the claimed invention is not supported by a specific asserted utility for the reasons just set forth, credibility cannot be assessed.

This is not to say that inventions that are to be used exclusively in a research setting (i.e., research tools) always lack a specific asserted utility. Indeed, many research tools such as telescopes, gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility. (See USPTO Utility Guidelines, page 12.) However, inventions that have a specifically identified utility must be distinguished from those whose utility requires further research to identify or reasonably confirm. (Id.) Research tools (such as gas chromatographs, screening assays, etc.) are useful in the sense that they can be used in conjunction with other method steps to evaluate materials other than themselves or to arrive at some result. The bi-ligands (common ligand – linker – specificity ligand) of the instant claims are not research tools in this sense. Rather, they are themselves the subject of basic research, whose usefulness or lack thereof has yet to be established. Merely labeling the instant libraries as "research tools" does not impart the specific utility required by this statute.

In the absence of an asserted specific utility, the "useful" requirement may be established by reference to a well-established utility. A "well established utility" is a "specific utility" which is well known, immediately apparent and implied by the specification based on the disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art. The bi-ligands (common ligand – linker – specificity ligand) of the instant claims are not supported by a well-established utility, however, because neither the specification as filed nor any art of record discloses or suggests any property or activity for the compounds such that another non-asserted utility

would be well established for the compounds. Further, the compounds of the instant claims are not recognizable as analogous to compounds with a recognized pharmacological (or other) activity. In the absence of any data as to their activity, there is no basis upon which to base either a specific or a well-established utility.

Claims 44-59 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 44-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 10/103,535. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 13-28 of the reference are drawn to method of identifying bi-ligand to a receptor, which would read on the instant claims (receptor is a genus, and the dehydrogenase is a species), and the claim 1 method of identifying a common ligand is required to practice the claimed method. Thus, the reference claims clearly read on the instant claimed method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

NOTE the assignee of the reference application is same as the instant application.

Response to Arguments

15. Applicant's arguments with respect to claims 44-59, filed in the after final amendment filed on 12/1/03 have been considered but are moot in view of the new ground(s) of rejection.

16. Upon further consideration the art rejections of record have been withdrawn.

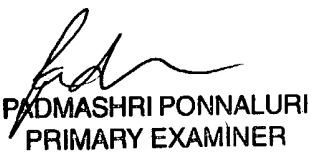
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner is on Increased Flex Schedule and can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

10 August 2004